UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

SERGEANTS BENEVOLENT ASSOCIATION HEALTH & WELFARE FUND, on behalf of itself and all others similarly situated, Plaintiff, vs. ALLERGAN, INC., Defendant.	Case No. _____ **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiff Sergeants Benevolent Association Health & Welfare Fund ("Sergeants"), on behalf of itself and all others similarly situated, brings this Class Action Complaint against Defendant Allergan Inc. ("Allergan" or "Defendant"), and alleges as follows.

I. NATURE OF THE ACTION

1. Allergan has reaped billions of dollars in profits from sales of its Restatis dry-eye drops. Restatis is a blockbuster drug and a key revenue source for Allergan that delivered nearly $1.5 billion in 2016 sales. This action arises because, instead of allowing its Restatis pharmaceutical patents to expire in the ordinary course, Allergan carried out a multifaceted scheme to prolong its Restatis monopoly and forestall the generic competition that should have, and otherwise would have, lowered prices for Sergeants and other end-payors. Each additional month of exclusive Restatis sales results in tens of millions of dollars in additional profits for Allergan.

2. Allergan abused legal process on a number of fronts to perpetuate a patent monopoly to which it was no longer entitled. It committed fraud on the Patent Office to gain

approval of a second wave of Restatis patents that never should have issued. It filed a set of sham citizen petitions with the FDA to delay approval of competing generic drugs. It pursued baseless infringement litigation against the generic drug makers that sought to compete in the Restatis market. And, facing a probable invalidity determination in an *inter pares* Patent Office proceeding, Allergan assigned the second wave of Restatis patents to a Mohawk Indian tribe in the hopes that borrowing the tribe's sovereign immunity (in exchange for a multi-million dollar reverse-licensing fee) could lend its patents the protection that the law does not afford. With these and other acts, Allergan manipulated the legal process to preserve its monopoly profits and foreclose generic entry, thereby preventing more affordable versions of Restatis from coming onto the market and causing end-payors to pay supracompetitive monopoly prices. Allergan's exclusionary conduct violates the antitrust laws.

3. Sitting by designation in a patent trial, a judge of the Federal Circuit declared Allergan's second wave of Restatis patents invalid on October 16, 2017. The court found, among other things, that Allergan's presentation to the Patent Office in 2013 "painted a false picture" as to the efficacy of the second-wave patents, "creat[ing] [a] misleading perception . . . . Allergan persuaded the examiner to issue the patent by way of a presentation that was more advocacy than science." The court concluded that "Allergan is not entitled to renewed patent rights for Restasis in the form of a second wave of patent protection" because "clear and convincing evidence" showed that the second-wave patents "are invalid for obviousness." In a separate order, the court stated that "sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities"—but "that is in essence is what the agreement between Allergan and the Tribe does" and "it is clear that Allergan's motivation for the assignment was to attempt to avoid the

IPR [*inter pares*] proceedings that are currently pending in the PTO by invoking the Tribe's sovereign immunity as a bar to those proceedings."

4. Sergeants seeks injunctive relief to end Allergan's wrongful monopoly conduct, together with damages for purchases and reimbursements of Restatis by Sergeants and other end-payors since May 17, 2014—when, but for Allergan's unlawful scheme, the Restatis market would have been opened to competition.

II. JURISDICTION AND VENUE

5. The Court has jurisdiction over Sergeants' claim for injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26. The Court also has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332(d), 1337(a), and 1367.

6. This Court has personal jurisdiction over Allergan because it purposefully directed its business activity toward this jurisdiction and had substantial contacts with this jurisdiction, and because Sergeants' claims for relief arise from and relate to illegal acts committed by Allergan within this jurisdiction. Sergeants paid unlawful overcharges for Restatis and suffered antitrust injury within this jurisdiction.

7. Venue is properly laid in this district under 28 U.S.C. §§ 1391(a), (b), (c), and (d), and 15 U.S.C. §§ 15(a) and 22. At all relevant times, Allergan transacted business in this district, and a substantial portion of the activity at issue in this case occurred in this district. Allergan at all relevant times maintained offices and engaged in significant business operations within 30 miles of this Court's Brooklyn courthouse, including Allergan's U.S. "Administrative Headquarters" in Parsippany, New Jersey and its U.S. sales offices in Jersey City, New Jersey.

8. Allergan's conduct alleged herein occurred within the flow of interstate commerce, including in this district, and was intended to and did have a direct and substantial

effect upon such commerce. At all relevant times, Allergan manufactured, distributed and sold Restasis in a continuous and uninterrupted flow of interstate commerce, including in this district.

III. PARTIES

9. Sergeants Benevolent Association Health & Welfare Fund ("Sergeants") is located in New York and was established for the purpose of providing benefits to approximately 4,700 active and 7,600 retired New York City Police Department Sergeants and their dependents. As a third-party payor of pharmaceutical claims for its members, Sergeants is an end-payor of Restatis and was thereby injured as a result of Allergan's unlawful behavior. Sergeants has purchased and/or provided reimbursement for Restatis during the class period, including in Arizona, California, Colorado, Connecticut, Florida, Kansas, Massachusetts, North Carolina, New Jersey, Nevada, New York, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and Washington. Sergeants expects that it will continue to purchase and/or provide reimbursement for Restasis and/or generic cyclosporine in the future.

10. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business in Irvine, California. Allergan filed and obtained approval of a New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark. Allergan also holds six second-wave patents that it asserts cover Restasis: U.S. Patent No. 8,629,111 (dated Jan. 14, 2014); U.S. Patent No. 8,633,162 (dated Jan. 21, 2014); U.S. Patent No. 8,642,556 (dated Feb. 4, 2014), U.S. Patent No. 8,648,048 (dated Feb. 11, 2014), U.S. Patent No. 8,685,930 (dated Apr. 1, 2014), and U.S. Patent No. 9,248,191 (dated Feb. 2, 2016) (together, the "second-wave patents"). As of September 8, 2017, Allergan assigned its ownership interest in the second-wave patents to the Saint Regis Mohawk Tribe (the "Mohawk Tribe").

11. All of the acts and omissions of Allergan detailed herein were part of, and in furtherance of, the unlawful course of conduct alleged herein, and were authorized, ordered, and/or carried out by Allergan's officers, agents, employees, or other representatives while actively engaged in the management of Allergan's affairs within the course and scope of their duties and employment, and with Allergan's actual or apparent authority.

IV. CLASS ACTION ALLEGATIONS

12. Sergeants brings this action under Federal Rules of Civil Procedure 23(a), (b)(1), and (b)(2), as representative of a class seeking injunctive relief ("injunctive relief class") and defined as follows:

> All persons or entities in the United States, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Restasis, other than for resale, from May 17, 2014 through the present (the "class period").

13. Sergeants also brings this action under Federal Rules of Civil Procedure 23(a) and (b)(3), as representative of a class seeking damages ("damages class") and defined as follows:

> All persons or entities in the United States, the District of Columbia, and Puerto Rico who, except within Ohio and Indiana, indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Restasis, other than for resale, during the class period, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries.

14. The following persons and entities are excluded from the injunctive relief class and the damages class (together, the "class"):

(a) Allergan, its officers, directors, employees, subsidiaries, and affiliates;

(b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans;

(c) all persons or entities who purchased Restasis for purposes of resale or directly from Allergan or its affiliates;

(d) fully insured health plans, *i.e.*, plans that purchased insurance covering 100% of their reimbursement obligation to members

(e) any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

(f) pharmacy benefit managers;

(g) all judges assigned to this case any members of their immediate families.

15. The class members are so numerous that joinder is impracticable. Members of the class are widely dispersed throughout the country. The class includes at least hundreds of thousands of consumers and at least thousands of third-party payors.

16. Plaintiff's claims are typical of the claims of all class members. Plaintiff's claims arise out of the same common course of anticompetitive conduct that gives rise to the claims of the other class members. Plaintiff and all class members were damaged by the same wrongful conduct, *i.e.*, they paid artificially inflated prices for Restatis, and were deprived of the benefits of competition, as a result of Defendant's conduct set forth herein.

17. Plaintiff will fairly and adequately protect and represent the interests of the class. Plaintiff's interests are coincident with, and not antagonistic to, those of the class.

18. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular expertise with class action antitrust litigation in the pharmaceutical industry.

19. Questions of law and fact common to the class members predominate over any questions that may affect only individual class members, because Defendant has acted on grounds generally applicable to the entire class.

20. Questions of law and fact common to the class include:

a. whether Allergan willfully obtained and/or maintained monopoly power in the market for Restasis and its generic equivalents;

b. whether Allergan procured the second-wave patents for Restatis by fraud;

c. whether Allergan unlawfully excluded competitors from the market for Restasis and its generic equivalents;

d. whether Allergan's overall course of conduct unlawfully prevented generic Restatis from entering the market;

e. whether Allergan entered into an illicit agreement in restraint of trade through its patent assignment and reverse-licensing deal with the Mohawk Tribe;

f. whether, and to what extent, Allergan's conduct caused antitrust injury to Plaintiff and the class;

g. whether, and to what extent, Allergan unjustly enriched itself to the detriment of Plaintiff and the class, warranting restitution or disgorgement;

h. what injunctive and other equitable relief is appropriate; and

i. what classwide measure of damages is appropriate.

21. Class treatment is a superior method for the fair and efficient adjudication of the controversy, because, among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a similar forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons and entities with a means of obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

22. Class treatment also is appropriate under Rule 23(b)(1) and/or (b)(2) because:

a. the prosecution of separate actions by individual class members would create a risk of inconsistent or varying adjudications which would establish incompatible standards of conduct for Defendant;

b. the prosecution of separate actions by individual class members would create a risk of adjudication of their rights that, as a practical matter, would be dispositive of the interests of other class members not parties to such adjudications or would substantially impair or impede other class members' ability to protect their interests; and

c. Defendant has acted and refused to act on grounds that apply generally to the class such that final injunctive relief and/or declaratory relief is warranted with respect to the class as a whole.

23. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

V. BACKGROUND ON DRUG PATENT PROCEDURES AND PRACTICES

24. Once lawful periods of patent exclusivity expire on branded drug products, generic manufacturers can seek Food and Drug Administration ("FDA") approval to market and sell generic versions of the branded drug. Under the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)—commonly known as Hatch-Waxman—competitors wishing to sell a generic equivalent of a branded drug must file an abbreviated new drug application ("ANDA"), which relies in substantial part on the scientific finding of safety and effectiveness included by the branded drug manufacturer in its New Drug Application ("NDA").

25. Accordingly, to gain FDA approval, generic drugs must be bioequivalent to their branded counterparts. While just as safe and effective as branded drugs, generic drugs are far less expensive.

26. As a result of substitution laws and other institutional features of pharmaceutical distribution and use, the launch of AB-rated generics causes a rapid price decline and shift from branded to generic drugs sales. Once a generic equivalent comes onto the market, it quickly captures sales of the corresponding branded drug. This results in a loss of revenue for the branded firm—but dramatic savings for the American public.

27. Generic manufacturers must wait until the expiration of all listed patents on a branded drug, unless they can certify that their generic product does not infringe the listed patents or that those patents are invalid. If a generic manufacturer certifies that the patent for the branded drug is invalid or not infringed (a "paragraph IV certification"), the branded patentee can sue the generic ANDA applicant for infringement—but it may do so only if it has an objectively reasonable basis to claim the patent's protection. If the brand files such an action within 45 days after receiving notice of the paragraph IV certification, the FDA will *not* grant final approval to the ANDA until the earlier of (a) 30 months' passage, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic ANDA. *Id.* §§ 355(c)(3)(C), (j)(5)(B)(iii). Hatch-Waxman infringement litigation thus provides the brand with a natural blocking mechanism, ripe for abuse.

28. To encourage incorrectly issued patents to be stripped from the economy, Congress in 2011 established an *inter partes* review process that empowers the Patent Trial and Appellate Board ("the Board") to determine the validity of a previously issued patent. If the Board determines that the challenger has a reasonable likelihood of prevailing on at least one of the challenged claims, it may conduct a trial on patent validity. A panel of three technically-trained administrative judges presides over these proceedings. The Board must resolve the challenge within one year after its filing—significantly faster than patent litigation in the federal

courts usually resolves. As such, *inter pares* review provides a relatively fast mechanism for an alleged patent infringer to challenge a patent issued in error.

29. Federal regulations also authorize the filing of citizen petitions with the FDA regarding safety, scientific, or legal concerns with a drug product, either before or after it enters the market, and requesting that the FDA take, or refrain from taking, any administrative action. Reviewing and responding to citizen petitions often consumes considerable time and resources. In addition to handling its regular workload, the FDA must: (a) research the subject matter of the citizen petition; (b) examine scientific, medical, legal and/or economic issues; (c) consider public responses to the citizen petition; and (d) coordinate internal agency review and clearance of the petition response.

30. Citizen petitions have become a prime vehicle for big pharmaceutical companies to delay generic entry and prolong their grip on the market for a given prescription drug. The resulting lag on generic competition can be very lucrative for a branded manufacturer that faces impending competition from an AB-rated generic drug.

31. Until a generic version of the branded drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the branded drug, and therefore the brand manufacturer can continue to profitably charge high monopoly prices. Companies like Allergan, aware of generics' rapid erosion of their branded sales, have an incentive to extend their monopoly for as long as possible, even, in some cases, through illegal means.

32. A branded drug company often develops its patent portfolios for a blockbuster drug like Restatis in a particular sequence. The first group of patents in the portfolio for the drug may reflect a genuine breakthrough contributing to the eventual success of the drug; these initial patents usually cover the active compound in a prescription drug or a particular pharmaceutical

composition and may be correspondingly robust. After filing applications for the original patents in the Patent and Trademark Office (the "Patent Office"), the company continues its research and development efforts in the hopes of developing a drug product that eventually could be approved by the FDA. As the company's research matures, its patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. The original patent filings, however, are now "prior art" that limits the scope of follow-on patents that can be obtained. New patents can be obtained for features of the drug only if the branded firm can show that the new features are non-obvious distinctions over the growing body of prior art. Over time, as the number of patent filings for the drug grows, so does the volume of prior art beyond which the branded firm must show non-obvious distinctions.

33. For a typical patent portfolio for a branded drug, its most significant patents issue first and, over time, the later-issued patents generally become increasingly narrow and harder to obtain. Even if the branded drug manufacturer is granted a patent with that narrower coverage, such later-issuing patents are more vulnerable to attack as invalid for covering subject matter that is old or obvious. In addition, generic firms can more easily design around the narrower coverage to avoid infringement.

VI. FACTUAL ALLEGATIONS

A. Dry-Eye Disease, Restatis, and Its Approval by the FDA

34. Cyclosporine treats dry-eye disease (also known as keratoconjunctivitis sicca), a painful condition involving abnormalities in the eye's tear film. Dry-eye disease occurs when the eye does not produce tears properly or when tears are not of the correct consistency and/or evaporate too quickly, and it is characterized by inflammation and damage to the ocular surface, resulting in blurry or fluctuating vision, as well as eye fatigue. Dry-eye disease

disproportionately afflicts the elderly, menopausal women, and those with systemic diseases like diabetes and rheumatoid arthritis. More severe cases of dry-eye disease can precipitate inflammation that can cause serious damage to the ocular surface.

35. Dry-eye disease can result in significant costs to patients, providers, and the overall healthcare system. Nearly 30 million Americans have symptoms of dry-eye disease, which are among the most common complaints patients report to eye-care professionals, and an estimated 16.4 million Americans report a dry-eye disease diagnosis from a physician. Nevertheless, only about 1 million patients currently receive prescription treatment for dry-eye disease. There is a large disparity between diagnosed and treated patients, and dry-eye disease remains an area of significant unmet need.

36. Allergan manufactures and sells the prescription drug cyclosporine under the brand name Restasis. Restatis is an emulsion with various components, including the active ingredient cyclosporin A, an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride. Restasis is one of the most widely prescribed drugs in the world. In 2016, U.S. sales of Restasis nearly reached $1.5 billion. The only drug that delivered more money to Allergan was Botox.

37. In 1993, Allergan obtained a license from Sandoz, Inc. that covered the technology of using cyclosporine to treat aqueous deficient dry-eye syndrome. That technology was the subject of U.S. Patent No. 4,839,342 issued to Renee Kaswan ("the '342 patent" or "the Kaswan patent"). The Kaswan patent claimed methods for enhancing or restoring lacrimal gland tearing consisting of topically administering cyclosporine to the eye in a pharmaceutically acceptable vehicle. The Kaswan patent recited the use of castor oil, among other compounds, as a pharmaceutically acceptable vehicle for such delivery.

38. Because cyclosporine is highly insoluble in water, Allergan had to develop an oil-in-water emulsion castor oil (a hydrophobic vehicle to dissolve the cyclosporine), together with an emulsifier and an emulsion stabilizer in water. Allergan disclosed this work in two patents, the first of which was U.S. Patent No. 5,474,979 ("the '979 patent" or "Ding I"), issued in 1995. Ding I contained four examples, the first two of which contained multiple formulations drawn from the disclosed and claimed ranges of components. This range included 0.05% to 0.40% cyclosporine and 0.625% to 5.00% castor oil. Ding I stated that the preferred weight ratio of cyclosporine to castor oil was below 0.16 (which is the maximum solubility level of cyclosporine in castor oil), and that the preferred weight ratio of cyclosporine to castor oil was between 0.02 and 0.12.

39. The second of Allergan's original Restatis patents, U.S. Patent No. 5,981,607 ("the '607 patent" or "Ding II"), is entitled "Emulsion Eye Drop for Alleviation of Dry Eye Related Symptoms in Dry Eye Patients and/or Contact Lens Wearers." The Ding II patent disclosed and claimed a method for alleviating dry-eye-related symptoms by topically applying to ocular tissue an emulsion of a higher fatty acid glyceride, polysorbate 80, and an emulsion-stabilizing amount of Pemulen in water, without cyclosporine.

40. Allergan then began clinical trials of various combinations of cyclosporine and castor oil. In its first clinical trial (the "Phase 2" study), Allergan tested many of the combinations listed in Ding I, attempting to ascertain the appropriate dosage (*e.g.*, 0.1% cyclosporine with 1.25% castor oil; 0.2% cyclosporine with 2.5% castor oil). The results were published in the periodical article Dara Stevenson et al., *Efficacy and Safety of Cyclosporin A Ophthalmic Emulsion in the Treatment of Moderate-to-severe Dry Eye Disease, A Dose-Ranging, Randomized Trial*, 107 Ophthalmology 967 (May 2000) ("Stevenson"). Stevenson

concluded that all tested concentrations significantly improved the ocular signs and symptoms of moderate-to-severe dry-eye disease, and mitigated its effects on vision-related functioning.

41. Stevenson further concluded that there was no clear dose-response relationship between the 0.05% cyclosporine formulation and formulations with greater amounts of cyclosporine—efficacy did not markedly increase with higher dosage. Even so, the 0.1% cyclosporine formulation "produced the most consistent improvement in objective and subjective endpoints," while the 0.05% cyclosporine formulation "produced the most consistent improvements in patient symptoms (such as sandy/gritty feeling and ocular dryness)." *Id.* at 974. Stevenson therefore recommended that "subsequent clinical studies should focus on the cyclosporine 0.05% and 0.1% formulations." *Id.*

42. Allergan's Phase 3 trials adopted that focus, and the results were published in Kenneth Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000) ("Sall"). Sall concluded that Phase 3 confirmed the results of Phase 2: 0.05% cyclosporine resulted in significantly greater improvements than castor oil alone, though castor oil by itself also produced significant improvements, suggesting it was a contributing factor to the formulations' success.

43. Neither Phase 2 nor Phase 3 found any significant difference in results between the 0.05% cyclosporine formulation and the 0.1% formulation.

44. Allergan filed an NDA with the FDA seeking authorization to market the 0.05% cyclosporine product tested in the Phase 3 trials. The proposed commercial product—Restasis—would contain all of the components of the Phase 3 0.05% cyclosporine formulation, including 1.25% castor oil as a delivery vehicle. The FDA approved the application in December 2002,

stating that "Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs."

B. Allergan's Second-Wave Patent Applications

45. Allergan's overarching scheme to extend its Restatis patent monopoly entailed several components, the first of which was to attempt to breathe new life into the monopoly by procuring new patents.

46. For over a decade after the FDA approved Allergan's Restasis NDA, Allergan filed a steady stream of patent applications involving combinations of cyclosporine and castor oil. Allergan did so despite prior art that rendered those applications devoid of merit: Earlier published work already covered a broad range of cyclosporine and castor oil combinations, with no statistically different outcomes based on the particular combination. Allergan filed U.S. Patent Application No. 10/927,857 ("the '857 application") on August 27, 2004. The '857 application involved cyclosporine and castor oil combinations within the range covered by Ding I. Allergan withdrew a number of the claims of the '857 application, and the Patent Office declined to grant the remaining claims, citing, in part, their obviousness in light of Ding I.

47. Allergan amended the '857 application in 2007 to include a claim to an emulsion comprising water, 1.25% castor oil and 0.05% cyclosporine—the same percentages as in Restasis—and the Patent Office again rejected it. Allergan appealed and, during the pendency of its appeal, Allergan filed a continuation of the '857 application, U.S. Patent Application No. 11/897,177 ("the '177 application"). The '177 application was similar to the '857 application, but added claims regarding new medical conditions that the method could treat.

48. In June 2009, Allergan admitted that the various composition claims in its '857 and '177 applications were obvious in light of Ding I. Allergan wrote that it "concede[d] that it would have been obvious to modify examples 1A-1E of the Ding reference to arrive at Composition II of the present application. The differences are insignificant." Allergan further admitted that the composition claims in the '857 and '177 applications were "squarely within the teaching of the Ding reference, and the Office should disregard any statements by the applicants suggesting otherwise, whether in [either the '857 or '177 applications]." Allergan withdrew its then-pending appeal of the Patent Office's rejection of its original '857 application.

49. Allergan then tried again to add another new claim regarding another composition of cyclosporine and castor oil. The Patent Office again rejected the new claim, including on the basis of its obviousness in light of Ding I. By April 2011, the Patent Office had entered a notice of abandonment on the '857 application. The '177 application ultimately issued as U.S. Patent No. 8,618,064, and was narrowly limited to additional use for treatment of corneal graft rejection.

50. In August 2013, Allergan filed six more continuation applications deriving from the '177 application. These applications claimed only minor variations from Allergan's earlier applications. They modified the prior specifications by adding four sentences detailing the role of cyclosporine as an immunosuppressant and the conditions that cyclosporine can treat. The patent judge who presided over the infringement trial found that "[t]he new applications were intended to protect the Restasis composition and the method of using that composition in treating dry eye and KCS after the expiration of the Ding I patent in 2014."

51. When it filed its 2013 applications, Allergan tried to backtrack from its concession that various cyclosporine-castor oil combinations were obvious in light of Ding I.

Specifically, Allergan claimed that new data supported patentability based on "unexpected" results demonstrating the claimed Restasis formulation to be particularly effective. The Patent Office rejected the claims in the 2013 applications as obvious in light of Ding I.

52. In response, Allergan submitted declarations executed in October 2013 by two of its scientists. Allergan represented to the Patent Office that one of its scientists, Dr. Rhett M. Schiffman, had determined that the Restasis formulations in the 2013 applications outperformed other combinations to a "surprising and unexpected" degree not anticipated by Ding I and the other prior art, with "8-fold" and "4-fold" increases in efficacy for the Schirmer Tear Test as compared with Allergan's Phase 2 and Phase 3 clinical trials.

53. Based solely on these representations, the Patent Office granted Allergan's six follow-on applications. These second-wave patents issued as U.S. Patent Nos. 8,629,111 ("the '111 patent"), 8,633,162 ("the '162 patent"), 8,642,556 ("the '556 patent"), 8,648,048 ("the '048 patent"), 8,685,930 ("the '930 patent"), and U.S. Patent No. 9,248,191 ("the '191 patent").

54. The "new" 2013 data was not, in fact, new and it did not demonstrate unexpected results. Dr. Schiffman's declaration contained statements plagiarized from the Sall article published 13 years earlier and described in paragraph 42, *supra*. Sall had relied on Allergan's own Restasis Phase 3 clinical trial data from the 1990s, and "[t]he actual clinical results, interpreted properly, show no significant difference in efficacy between the Restasis formulation and the 0.1% formulation that was Example 1D of the Ding I patent," the patent court found.

55. Allergan made its 2013 representations and characterizations to the Patent Office, by both commission and omission, with specific intent to deceive the Patent Office. The representations and characterizations were material and fraudulently induced the Patent Office to grant the second-wave patents. Had Allergan disclosed to the Patent Office that Dr. Shiffman's

statements and cited data were taken from prior art known to Allergan for over 10 years, as its duties required, the Patent Office would have denied all of the 2013 applications for the same reasons it had repeatedly denied each prior such application: the claims presented were obvious in light of the prior art.

C. Allergan's Orange Book Listing of the Second-Wave Patents; Subsequent Generic ANDAs

56. The second-wave patents issued beginning on January 14, 2014, starting with the '111 patent, which Allergan immediately submitted to the FDA for listing in the "Orange Book" (the publicly available "Approved Drug Products with Therapeutic Equivalence Evaluations"). Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents being claimed as related to the branded drug. FDA rules permit a brand manufacturer to list patents in the "Orange Book" only if they are reasonably enforceable. An FDA form expressly asks the applicant whether the drug presents a "No Relevant Patent" situation—that is, a situation in which no patents could be reasonably asserted in an infringement lawsuit.

57. Allergan's listing of the '111 and other second-wave patents in the Orange Book violated FDA rules and guidelines because those patents could not be reasonably asserted in an infringement lawsuit. Allergan knew when it listed the second-wave patents in the Orange Book that the patents were invalid, but that they could nonetheless be used to delay generic competition to Restasis well beyond May 2014. By listing its fraudulently obtained second-wave patents in the Orange Book, Allergan was able to game the regulatory system to prevent approval of competing generic versions of Restasis.

58. Before the '111 patent issued, the FDA had received at least one ANDA for a generic version of Restasis. If approved, that generic drug could have been marketed once the Ding I patent expired, in May 2014. Allergan's Orange Book listing, however, required any

ANDA filer seeking to market a generic version of Restasis to file a certification as to the "new" '111 patent. As a result, ANDA filers now had to include paragraph IV certifications with respect to the '111 patent (and eventually the other second-wave patents as well). ANDA applicants' paragraph IV certifications with respect to the second-wave patents, in turn, enabled Allergan to sue for infringement under Hatch-Waxman and thereby trigger the automatic stay of FDA approval of the allegedly infringing ANDA for up to 30 months.

59. Beginning in 2011, several generic drug manufacturers submitted ANDAs seeking FDA approval to market and sell generic Restasis. The generic drug manufacturers that have submitted Restatis ANDAs include Watson, Teva, Mylan, Akorn, Apotex, Innopharma (a Pfizer subsidiary), Famy Care, TWi Pharmaceuticals, and Deva Holding.

60. Absent Allergan's abuse of process, one or more of these ANDA filers would have received FDA approval and produced sufficient quantities of generic Restasis to supply the market when Ding I expired. But for the administrative delays and drain in FDA resources that resulted from Allergan's improper Orange Book listings, infringement suits, and citizen petitions, at least some of these generic manufacturers would have been approved and on the market as early as May 2014—over 30 months after the first Restasis ANDA was filed—and in any case well before now.

61. Public statements of executives of would-be generic competitors for Restatis sales demonstrate those firms' readiness to enter the Restatis market. In a June 2016 earnings call, Akorn stated that it had "already partnered with someone to manufacture the [Restasis generic] product," that the manufacturing partnership had "already been lined up and filed," and that Akorn had responded to FDA follow-up inquiries and was anticipating "product approval hoping in the near future." In an October 2015 earnings call, Mylan's president stated that Mylan had

filed its Restasis ANDA "a couple of years back" and was poised to launch its Restasis generic products upon FDA approval.

D. Allergan's Infringement Suits

62. Generic drug makers Akorn, Mylan, Teva, Apotex, and Pfizer's subsidiary Innopharma submitted paragraph IV certifications within weeks of each other beginning in July 2015, asserting that the second-wave patents were either invalid or noninfringed because Allergan fraudulent procured them and they are obvious in light of Ding I and other prior art. Allergan responded to each paragraph IV certification by filing patent infringement actions in federal district court in the Eastern District of Texas, beginning on August 24, 2015.

63. These infringement suits triggered the automatic 30-month stay of any FDA final approval of these ANDAs, thus providing Allergan with an unlawful extension of its monopoly.

64. On October 16, 2017, following a bench trial, the court declared the second-wave patents invalid as obvious. The court's post-trial statements and findings include the following:

- "Allergan persuaded the examiner to issue the patent by way of a presentation that was more advocacy than science. The presentation suggested that the Restasis formulation resulted in efficacy levels up to eight times as great as would be expected . . . . In fact, a closer examination of the results of the clinical studies on which Allergan relied makes it clear that the presentation to the PTO substantially overstated the difference . . . . The actual clinical results, interpreted properly, show no significant difference in efficacy[.]"

- "[T]he presentation made to the examiner in 2013 . . . painted a false picture . . . . [and] created [a] misleading perception[.]"

- "[T]here is a dearth of evidence showing any real difference between the efficacy of the 0.05% and 0.1% cyclosporin formulations in Phase 2, as presented in Stevenson, and in Phase 3, as presented in Sall. A person of skill reviewing those papers would come to the conclusion that neither formulation was more effective than the other in Phase 2. That person of skill would reach the same conclusion for Phase 3."

- "Allergan is not entitled to renewed patent rights for Restasis in the form of

a second wave of patent protection. . . . [T]he defendants have proved by clear and convincing evidence that the asserted claims of the Restasis patents are invalid for obviousness."

- "Allergan introduced evidence that Restasis has generated very large sales and considerable profits. In the year 2015, for example, Restasis had net sales of $1.2 billion on which the company generated a pre-tax profit of approximately $975 million. . . . Allergan was able to foreclose competition in cyclosporin/glyceride emulsion formulations from the early 1990s until 2014."

- "[S]overeign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities. . . . [T]hat is in essence is what the agreement between Allergan and the Tribe does . . . . [I]t is clear that Allergan's motivation for the assignment was to attempt to avoid the IPR [*inter pares*] proceedings that are currently pending in the PTO by invoking the Tribe's sovereign immunity[.]"

- "The Court has serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed. The essence of the matter is this: Allergan purports to have sold the patents to the Tribe, but in reality it has paid the Tribe to allow Allergan to purchase—or perhaps more precisely, to rent—the Tribe's sovereign immunity[.]"

65. Allergan brought its infringement suits despite knowing that they were objectively baseless and no reasonable patent holder in Allergan's position could expect to prevail. In 2009 Allergan itself took the position (which it later rescinded) that the claims in the '857 and '177 applications—which formed the basis for the second-wave patents—were obvious in light of Ding I. Allergan also knew that it had obtained the second-wave patents only by virtue of its fraudulent misrepresentations and omissions to the Patent Office.

66. Allergan brought its infringement suits not to protect legitimately secured patents but to exploit the judicial machinery to delay generic competition to its Restasis monopoly. For a $1.5 billion per year franchise, every additional month Allergan could postpone competition from generic Restasis added another $125 million to its revenues. Allergan's own infringement complaint evidences its goal of delaying the regulatory approval process; Allergan asked the

court to order that "the effective date of any FDA approval" of any Restasis ANDA be "a date which is not earlier than the latest expiration date . . . including any extensions or periods of exclusivity" for the second-wave patents.

E. Allergan's Serial Citizen Petitions

67. On another front, Allergan purposefully obstructed the FDA's processes for approving the generic Restatis ANDAs with a series of baseless citizen petitions.

68. On January 15, 2014, the day after Allergan listed the first of the second-wave patents in the Orange Book, Allergan filed a citizen petition relating to the FDA's non-binding June 2013 draft guidance to Restasis ANDA applicants, and then filed a superseding citizen petition on February 28, 2014. The FDA's guidance document stated that, to establish generic Restasis' bioequivalence with its branded counterpart, the ANDA applicants could use one or both of: (1) in vivo testing (i.e., testing on live humans, often referred to as "clinical endpoint studies"); or (2) in vitro testing (i.e., in a test tube). Generic drug makers typically use in vitro testing in their ANDAs to demonstrate bioequivalence with a branded drug, because it is significantly less expensive and time-consuming than the in vivo clinical trials that brand manufacturers generally must undertake as part of a successful NDA.

69. Allergan's citizen petition asked the FDA to "refus[e] to accept or approve any [Restasis] ANDA if it does not include data from one or more appropriately designed comparative clinical trials to demonstrate bioequivalence." Claiming that "a delay is necessary to protect the public health," Allergan asked the FDA to withdraw the guidance and impose onerous conditions before approving any Restasis ANDA. Allergan failed to disclose that it had paid substantial sums to the doctors who submitted comments in support of its petition.

70. Allergan had already conveyed these same views on the draft guidance to the FDA on August 17, 2013. To its shareholders, Allergan touted its citizen petitions as an effective response to "intense competition from generic drug manufacturers."

71. On November 20, 2014, the FDA rejected the six requests in Allergan's citizen petition. The FDA advised that the in vitro-only option in its June 2013 draft guidance was consistent with "[t]he Agency's authority to make bioequivalence determinations on a case-by-case basis using in vivo, in vitro, or both types of data," which enables the FDA "to effectuate several long-recognized policies that protect the public health" when approving generic ANDAs. The FDA granted Allergan's request only to the limited extent that Allergan had requested notice and an opportunity to comment on the FDA's recommended bioequivalence methodology, and the FDA agreed to explain the scientific basis for allowing ANDA applications to rely solely on in vitro studies to show bioequivalence.

72. As the FDA explained in denying the petition, for drugs that are primarily absorbed systemically, in vivo studies are often preferred, but such studies are "usually of limited utility for locally acting, non-systemically absorbed drug products" like Restasis. In fact, "an in vitro study is likely more sensitive, accurate, and reproducible than a comparative clinical endpoint study to establish bioequivalence" of generic Restatis. Clinical trials, the FDA advised, "likely would not be as reliable at detecting differences in the formulation and manufacturing process of a proposed generic product when [Restasis] shows only a modest clinical effect," particularly given "that such trials may present economic and logistical changes for ANDA sponsors."

73. Allergan filed another citizen petition on December 23, 2014, largely making the same arguments Allergan had advanced in its previous petitions. Allergan then supplemented its

December petition on four separate occasions. On August 16, 2015, Allergan asked the FDA to convene a committee of outside experts to evaluate the use of in vitro methods, and to decline to receive, review, or approve any Restatis ANDAs until the committee reported back.

74. The FDA largely denied Allergan's serial petitions on February 10, 2016, noting that Allergan's December 2014 petition "repeats many of the assertions that were at the center of Allergan's previous petition"—so there was no need to repeat the FDA's substantive responses. Further commenting on Allergan's claims, the FDA stated that they "[n]ot only . . . lack legal support, they also rest on flawed logic." Nonetheless, the FDA was obligated to respond specifically to each of Allergan's requests, and stated in its February 10, 2016 letter that it would "not approve or receive any ANDA referencing Restasis based on in vitro assays unless and until FDA responds specifically to the findings of Allergan's testing of nine experimental test emulsions" submitted with its December 2014 petition. In other words, the FDA was delaying its approval of any Restasis ANDA because of Allergan's serial citizen petition campaign.

75. Allergan continued pressing the same arguments with the FDA. In its latest citizen petition, filed on August 4, 2017, Allergan again asked the FDA to refrain from approving any generic Restatis ANDAs unless they were supported by in vivo studies.

F. Allergan's Assignment and Reverse-Licensing Deal with the Mohawk Tribe

76. In June 2015, Apotex, a Restatis ANDA applicant, petitioned the Patent Trial and Appellate Board to conduct an *inter pares* review of Allergan's second-wave patents for Restatis. Allergan settled that proceeding with Apotex in December 2015, on undisclosed terms. By that time, Mylan and Teva also had petitioned the Board to conduct the same *inter pares* review. In December 2016, the Board found a reasonable likelihood that all of the second-wave patents would be invalidated upon further review.

77. On September 8, 2017, Allergan entered into an agreement with the Mohawk Tribe for the improper purpose of evading an invalidation finding by the Board by invoking the tribe's sovereign immunity. Under their agreement, Allergan assigned the second-wave patents to the tribe, and the tribe agreed to license the patents back to Allergan in exchange for $13.75 million, in addition to potential annual royalties of $15 million. The tribe is not otherwise involved in the pharmaceutical business.

78. On September 22, 2017, Allergan petitioned the Board to dismiss the pending *inter pares* proceedings on the basis of tribal sovereign immunity.

79. Allergan has been open about its bad-faith motive for striking its deal with the Mohawk Tribe. Allergan's chief executive, Brent Saunders, stated that Allergan entered into this agreement to avoid "double jeopardy"—that is, to disrupt adjudicative proceedings in one of two venues, the Patent Office and the Eastern District of Texas.

VII. MARKET POWER AND DEFINITION

80. The relevant geographic market is the United States and its territories and possessions.

81. Allergan's market power may be shown directly, and therefore no relevant market needs to be defined. To the extent Plaintiff may need to show market power indirectly, the relevant product market is the sale of cyclosporine ophthalmic emulsion products, and consists of Restasis and any AB-rated generic equivalents.

82. Allergan's share of the relevant market has always been 100 percent.

83. Allergan has always held monopoly power in the relevant market. It had—and has—the power to maintain the price of Restasis at supracompetitive levels without losing substantial sales to other products.

84. Direct evidence shows that (a) but for Allergan's anticompetitive conduct, generic versions of Restasis would have entered the market at substantially lower prices than branded Restasis; (b) Allergan's gross margin on Restasis was at all times at least 60%; and (c) Allergan never lowered Restatis prices in response to the pricing of other branded or generic drugs.

85. Allergan doubled the price of Restasis over the past decade.

86. Allergan sold Restasis far in excess of marginal costs, far in excess of the competitive price, and enjoyed unusually high profit margins.

87. Allergan has held monopoly power conferred by the Ding I patent since 1995 and has enjoyed large financial gain from its Restatis monopoly since 2003, when it launched Restasis upon FDA approval.

88. Manufacturers differentiate branded drugs like Restasis based upon features and benefits (including safety and efficacy), and not based upon price. Doctors and patients are generally price-insensitive when prescribing and purchasing prescription drugs like Restasis, in part because insurers typically bear much of the cost of prescriptions. Even drugs within its same therapeutic class do not constrain the price of Restasis.

89. Restasis is not reasonably interchangeable with any products apart from AB-rated generic versions of Restasis. The attributes of Restasis significantly differentiate it from other treatments for dry-eye disease. The FDA does not regard Restasis and other dry-eye disease treatments as interchangeable. When Restatis received FDA approval, in December 2002, Allergan characterized Restasis as "the first and only therapy for patients with keratoconjunctivitis sicca (chronic dry eye disease-CDED) whose tear production is presumed to be suppressed due to ocular inflammation." In filings with the FDA, Allergan has similarly highlighted Restasis' uniqueness: "RESTASIS is a pathbreaking product that was developed to

treat the widespread and sometimes debilitating problem of dry eye disease. Before RESTASIS, dry eye disease was a largely unmet medical need. After years of FDA-required clinical trials, Allergan was able to produce a precisely formulated drug that has significant efficacy in treating dry eye disease."

90. Other products are not practical substitutes for Restatis. Artificial tears offer only temporary relief without addressing the underlying causes of DED. Although corticosteroids can address the inflammation associated with DED, they have unwanted side effects, as do devices like "punctal plugs" that block the tear ducts and help the eye retain naturally produced tears.

91. That Allergan has doubled the price of Restasis over the past decade without losing significant sales further demonstrates the lack of substitutability between Restasis and other drug products.

92. Restasis does not exhibit significant, positive cross-elasticity of demand with any other dry-eye disease medication. Various other treatments for dry-eye disease may exist, but none exhibit cross price elasticity with—and hence do not constrain the price of—Restasis. The existence of non-cyclosporine products that may be used to treat similar indications as Restasis did not constrain Allergan's ability to raise or maintain Restasis prices without losing substantial sales, and therefore those other drug products do not occupy the same relevant antitrust market as Restasis. Therapeutic alternatives are not the same as economic alternatives.

93. Functional similarities between Restasis and other dry-eye disease medications, other than AB-rated generic Restasis equivalents, are insufficient to permit inclusion of those other molecules in the relevant market with Restasis. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that

would otherwise prevail in a competitive market. No other dry-eye disease medication will make inroads on Restatis sales sufficient to prevent Allergan from raising or maintaining the price of Restasis above levels that would otherwise prevail in a competitive market.

94. Allergan needed to control only Restasis, and no other products, to maintain the price of Restasis profitably at supracompetitive prices while preserving all or virtually all of its sales. Only market entry of a competing, AB-rated generic version of Restasis would render Allergan unable to profitably maintain its Restasis prices without losing substantial sales.

95. Allergan exercised and continues to exercise its monopoly power to exclude competition to Restasis and its AB-rated equivalents.

VIII. MARKET EFFECTS AND CLASS DAMAGES

96. But for the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market with their generic Restatis products as early as May 17, 2014, when the exclusivities associated with Ding I and related patents expired. Instead, Allergan willfully and unlawfully maintained its Restatis monopoly power through an unified scheme to exclude competition. Allergan's scheme prevented generic competition and had its intended effect of permitting Allergan to maintain supracompetitive monopoly prices for Restasis. Allergan implemented its scheme by fraudulently obtaining the second-wave patents, wrongfully and knowingly submitting these invalid patents for listing in the Orange Book, prosecuting sham patent infringement lawsuits against the putative generic manufacturers, submitting sham citizen petitions to the FDA and otherwise abusing the Hatch-Waxman framework, and striking a deal with the Mohawk Tribe in a naked attempt to insulate the second-wave patents from invalidation in the Patent Office. These acts, individually and in combination, were unreasonably anticompetitive and unlawful.

97. Had Allergan not defrauded the Patent Office, (a) the second-wave patents would not have issued, (b) Allergan could not have initiated sham litigation based those patents to block FDA approval of all putative generic alternatives to Restatis, and (iii) AB-rated generic Restasis manufacturers would have launched their generic products by May 17, 2014.

98. Allergan's conduct had the purpose and effect of foreclosing generic competition to Restasis. Allergan's conduct enabled it to maintain its monopoly, exclude competition in the relevant market, and charge high monopoly prices without losing significant sales.

99. But for Allergan's unlawful exclusionary conduct, one or more of the ANDA filers would have begun marketing and selling generic versions of Restasis by May 17, 2014. The generic manufacturers seeking to sell generic Restatis have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic drug products, and manufacturing commercial-launch quantities sufficient to meet market demand. Absent Allergan's unlawful conduct, these firms would have been ready, willing, and able to launch generic versions of Restasis by May 17, 2014.

100. Allergan's anticompetitive conduct has caused and will cause Sergeants and the class members to pay more than they would have paid for Restasis, absent that conduct.

101. Typically, generic versions of branded drugs are initially priced significantly below the corresponding reference branded counterpart. As a result, upon generic entry, end-payors' purchases of branded drugs are rapidly replaced by generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decline even further due to competition among the generic firms, and, correspondingly, the branded drug continues to lose even more market share to the generic versions of the drug.

102. Price competition enables all purchasers of the drug to purchase generic equivalents of a drug at substantially lower prices or to purchase the branded drug at reduced prices. Consequently, brand manufacturers have a strong incentive to delay generic competition, and substantial price inflation results from that delay.

103. If generic competitors had not been unlawfully prevented from entering the Restatis market earlier and competing with Allergan, end-payors like Sergeants would have paid less for cyclosporine ophthalmic emulsion by (a) substituting purchases of AB-rated generic Restasis for their purchases of more-expensive branded Restasis, (b) receiving discounts on their remaining branded Restasis purchases, and/or (c) purchasing generic Restasis at lower prices sooner.

104. Allergan's unlawful conduct deprived Sergeants and the class of the benefits of competition that the antitrust laws were designed to guarantee.

IX. ANTITRUST IMPACT

105. The effect of Allergan's course of monopolistic conduct was to net Allergan billions of dollars in revenue at the expense of end-payors, including Sergeants and the proposed class. Allergan's antitrust violations deprived Sergeants and the class members of the opportunity to purchase generic versions of Restasis, causing them to pay hundreds of millions of dollars in unlawful overcharges.

106. During the relevant period, Sergeants and class members purchased substantial amounts of Restasis indirectly from Allergan. The overcharges resulting from Defendants' conduct are directly traceable through the pharmaceutical distribution chain to Sergeants and other end-payors. A manufacturer first sells the drug to direct purchaser wholesalers based on the listed WAC, minus applicable discounts. Wholesalers then sell the drug to pharmacies, which in turn sell the drugs to consumers. In this short chain of distribution, drug products are

not altered or incorporated into other products. Each drug purchase is documented and closely tracked by pharmacies, pharmacy benefit managers, and third-party payors (such as health and welfare funds). The products and their prices are thus directly traceable from the manufacturer until they reach the hands of the consumer at a pharmacy.

107. As a direct and proximate result of Allergan's unlawful anticompetitive conduct, Sergeants and class members paid monopoly prices for Restatis that were substantially higher than the prices they would have paid absent Allergan's illegal conduct, because: (1) the price of branded Restasis was artificially inflated as a result of Allergan's illegal conduct, and (2) the class members were deprived of the opportunity to purchase lower-priced generic versions of Restasis sooner.

108. In consequence, Sergeants and class members have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. INTERSTATE AND INTRASTATE COMMERCE

109. At all material times, Allergan manufactured, marketed, promoted, distributed, and sold substantial amounts of Restasis in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

110. At all material times, Allergan transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Restasis.

111. In furtherance of its efforts to restrain competition in the relevant market, Allergan employed the U.S. mails and interstate and international phone lines, as well as means of interstate and international travel. Allergan's activities were within the flow of and have substantially affected interstate commerce.

112. Allergan's anticompetitive conduct also had substantial intrastate effects in that, among other things, retailers within each state were prevented from offering more affordable generic Restasis to end-payors inside each respective state. The continued absence of competition from generic Restasis directly affects and disrupts commerce within each state.

XI. CONTINUING VIOLATIONS

113. Allergan engaged in and continues to engage in a course of wrongful conduct, including conduct within the applicable limitations periods. Allergan's conduct has inflicted continuing harm within the applicable statutes of limitations. Sergeants and class members accordingly can recover for damages sustained during the applicable limitations periods.

XII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Monopolization in Violation of State Antitrust Law

114. Sergeants incorporates the above paragraphs by reference.

115. From 1995 until the present, and with continuing future effects, Allergan possessed and continues to unlawfully possess monopoly power in the market for Restasis (cyclosporine ophthalmic emulsion). During this time, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

116. Allergan has willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014, through at least the present. Allergan has done so by executing a multifaceted anticompetitive scheme to prevent AB-rated generic versions of Restasis from entering the market. Each and every component of Allergan's scheme, individually and collectively, was designed to, and did, foreclose generic competition in violation of law. The components of Allergan's scheme include:

a. Prosecuting serial baseless patent applications and ultimately obtaining

the second-wave patents through fraud on the Patent Office;

b. Improperly listing the second-wave patents in the Orange Book;

c. Deploying the second-wave patents to foreclose generic competition with multiple baseless infringement suits;

d. Submitting serial baseless citizen petitions to the FDA; and

e. Abusing the Patent Trial and Appeal Board's *inter partes* review process through an anticompetitive assignment of the second-wave patents to the Mohawk Tribe, in exchange for a multi-million dollar reverse-licensing fee paid by Allergan.

117. Allergan knowingly and intentionally committed fraud under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), to induce the Patent Office to grant the second-wave patents. After repeated denials of earlier, substantially similar applications over more than 10 years, Allergan submitted false sworn declarations in the Patent Office in 2013.

118. Allergan, by and through its patent attorneys and scientists who submitted declarations in support of patentability (including Laura L. Wine, Dr. Rhett M. Schiffman, and Dr. Mayasa Attar), made misrepresentations of fact to the Patent Office, including:

a. Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed that, "surprisingly, the claimed formulation demonstrated a 8-fold increase in relative efficacy for the Schirmer Teat Test score in the first study of Allergan's Phase 3 trials compares to the relative efficacy for the . . . formulation discussed in Example 1E of Ding, tested in Phase 2 trials . . . . This was clearly a very surprising and unexpected result."

b. Dr. Schiffman did not disclose to the Patent Office that the data provided was taken from the Sall paper published more than a dozen years earlier (and three years before the priority date for the Restasis patents). Even if the results were surprising (and they were not), they were publicly known before the date of invention and thus cannot support a well-founded claim that the results were "unexpected."

c. Figures 1-4 in Dr. Schiffman's declaration reported figured from the earlier Sall paper but omitted all error bars and p-values. In reality, as the

patent court found, none of the pair-wise comparisons between the two cyclosporine formulations for corneal staining and Schirmer scores in the Phase 2 study or the pooled Phase 3 studies demonstrated statistical significance at any time point, and many of the p-values for the pair-wise comparisons were very high. The actual statistical analyses showed that any observed difference in raw numbers between the cyclosporine formulations was likely the product of random chance.

d. Dr. Schiffman did not disclose to the Patent Office that he was comparing different Schirmer tear test scores—one without anesthesia in Phase 2 and one with anesthesia in Phase 3—in an effort to show a difference in efficacy. As the patent court found, only the Schirmer Tear Test results with anesthesia in Phase 3 significantly favored the 0.05% cyclosporine formulation: "It was therefore only by comparing the results of two different types of tests that Dr. Schiffman was able to produce a significantly distorted picture suggesting that the 0.05% cyclosporin/1.25% castor oil formulation in Phase 3 was much more effective than the 0.05% cyclosporin/0.625% castor oil formulation in Phase 2." This was both statistically and clinically improper.

e. Dr. Schiffman did not disclose to the Patent Office that his chosen method for calculating the differences in efficacy "exaggerated the difference in the raw values between the two," the patent court found.

f. The calculations in Dr. Schiffman's table are misleading in several respects: (1) Dr. Schiffman used ratios of the degree of improvement, which tends to overstate the difference between the results; (2) Dr. Schiffman ignored the fact that the Phase 2 study was quite small, and that the difference in the raw numbers between formulations was not statistically significant; and (3) Dr. Schiffman only included data from favorable comparisons between the two formulations while omitting categories in which the Ding I formulation performed better than the second-wave formulation.

119. Had Allergan refrained from making these misrepresentations, and instead disclosed to the Patent Office examiner that the 2013 data were taken from prior art known to Allergan for over 10 years—as Allergan's duty of disclosure, candor, and good faith required—the examiner would have rejected all of the 2013 applications for the same reasons the Patent Office had repeatedly denied each of Allergan's earlier applications: the claims presented were obvious in light of the prior art. Allergan's misstatements in the Patent Office were material,

fraudulent, and made knowingly and with the intent to deceive, and in fact induced the Patent Office to issue the second-wave patents.

120. Before Allergan's misleading statements and omissions, the Patent Office had repeatedly rejected the applications as obvious. The Patent Office had also earlier rebuffed Allergan's purported secondary considerations of non-obviousness (including commercial success and unmet need). The decision of the patent judge, sitting by designation in the Eastern District of Texas, corroborates the material nature of Allergan's misleading statements and omissions.

121. Allergan made these statements with specific intent to deceive the Patent Office. Allergan's motive was to obtain a longer period of patent protection, given the large sales of Restasis and the importance of the product to the company. Allergan made its misleading statements only after the examiner had rejected the application—not with the initial filing—with the purpose and effect of overcoming that rejection and securing patentability through fraud.

122. The Patent Office reasonably relied on Allergan's false and misleading statements in issuing the second-wave patents. The examiner stated that the Schiffman declaration was sufficient to overcome the earlier rejection based on Ding I because, "unexpectedly, the claimed formulation . . . demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Phase 3 trials compared to relative efficacy for the formulation disclosed in Ding I." The examiner further stated that the declarations "illustrate that the claimed formulations . . . demonstrate a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3

studies compare to the . . . formulation tested in Phase 2 and disclosed in Ding . . . ."

123. But for Allergan's misrepresentations and omissions, the second-wave patents would not have issued. Absent their issuance, generic versions of Restasis would have entered the market, unobstructed by any patent rights, beginning on May 17, 2014.

124. Allergan knew when it listed the second-wave patents in the Orange Book that these patents were fraudulently procured and were otherwise invalid as obvious in light of prior art, namely Ding I and the related patents, and that it was therefore improper to list the second-wave patents in the Orange Book. Allergan knew that listing the second-wave patents in the Orange Book would cause ANDA applicants to file paragraph IV certifications, thereby allowing Allergan to file patent infringement suits against those applicants that would trigger an automatic stay of FDA final approval of their generic Restasis product for up to 30 months, despite those suits' objective baselessness.

125. Allergan knowingly and intentionally filed and pursued multiple sham litigations against manufacturers of AB-rated generic equivalents of Restasis that no reasonable pharmaceutical company in Allergan's position would have realistically expected to win. Allergan intentionally and misleadingly alleged the generic manufacturers' products infringed its second-wave patents, despite knowing when those suits were filed that those patents were wrongfully obtained though fraud on the PTO and were otherwise invalid as obvious in light of the prior art, namely Ding I and the related patents. Allergan also knew, at the time that it filed those multiple sham suits, that it had no realistic likelihood of success on the merits of those claims. No reasonable fact-finder would enforce the fraudulently procured and otherwise invalid second-wave patents against a generic drug manufacturer. Allergan knew, therefore, that no reasonable drug manufacturer would have believed it had a

reasonable chance of succeeding on the merits of these infringement lawsuits. Allergan intentionally filed its objectively baseless infringement litigation for an improper purpose: to enlist the judicial process as an anticompetitive weapon to keep generics off the market and wrongfully maintain its monopoly power over Restasis.

126. Allergan knowingly and intentionally submitted a series of citizen and other petitions to the FDA when no reasonable pharmaceutical manufacturer in Allergan's position would have expected the FDA to grant the requested relief. The purpose and effect of these petitions was to delay the FDA's approval of any of the pending generic ANDA applications. The citizen petitions had no legitimate purpose and lacked all merit.

127. Allergan knowingly and intentionally transferred the second-wave patents to the Mohawk Tribe—a sovereign tribe that does not manufacture or distribute pharmaceutical products of any kind and is better known for its operation of casinos on tribal lands in New York—in an attempt to evade invalidation of those patents and cessation of its Restasis monopoly. The deal with the tribe corroborates Allergan's bad faith and willingness to take any step, regardless of legality, to perpetuate its Restatis monopoly and the profits flowing therefrom.

128. No immunity shields Allergan's anticompetitive conduct from condemnation.

129. No valid procompetitive business justification for Allergan's anticompetitive conduct exists, and the anticompetitive harm from Allergan's conduct greatly outweighs any conceivable procompetitive benefit.

130. By engaging in the foregoing conduct, Allergan has intentionally and wrongfully maintained monopoly power in the relevant market, in violation of the following state laws:

a. Ala. Code § 6-5-60 with respect to purchases in Alabama by class members and/or purchases by Alabama residents.

b. Ariz. Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by class members and/or purchases by Arizona residents.

c. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by class members and/or purchases by California residents.

d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in D.C. by class members and/or purchases by D.C. residents.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by class members and/or purchases by Florida residents.

f. Haw. Rev. Stat. §§ 480-1, *et seq.*, with respect to purchases in Hawaii by class members and/or purchases by Hawaii residents.

g. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases in Illinois by class members and/or purchases by Illinois residents.

h. Iowa Code § 553.5 *et seq.*, with respect to purchases in Iowa by class members and/or purchases by Iowa residents.

i. Kansas Stat. Ann. § 50-161(b), *et seq.*, with respect to purchases in Kansas by class members and/or purchases by Kansas residents.

j. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by class members and/or purchases by Massachusetts end-payors paying substantially higher prices for Restatis in actions and transactions occurring substantially within Massachusetts.

k. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by class members and/or purchases by Maine residents.

l. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by class members and/or purchases by Michigan residents.

m. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by class members and/or purchases by Minnesota residents.

n. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases

in Mississippi by class members and/or purchases by Mississippi residents.

o. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchases in Missouri by class members and/or purchases by Missouri residents.

p. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by class members and/or purchases by Nebraska residents.

q. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by class members and/or purchases by Nevada residents.

r. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases in New Hampshire by class members and/or purchases by New Hampshire residents.

s. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by class members and/or purchases by New Mexico residents.

t. N.Y. Gen. Bus. Law § 340 with respect to purchases in New York by class members and/or purchases by New York residents.

u. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by class members and/or purchases by North Carolina residents.

v. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by class members and/or purchases by North Dakota residents.

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by class members and/or purchases by Oregon residents.

x. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by class members and/or purchases by Puerto Rico residents.

y. R.I. Gen. Laws §§ 6-36-5 *et seq.,* with respect to purchases in Rhode Island by class members and/or purchases by Rhode Island residents.

z. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by class members and/or purchases by South Dakota residents.

aa. Tenn. Code Ann §§ 47-25-101, *et seq.,* with respect to purchases in Tennessee by class members and/or purchases by Tennessee residents.

bb. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by class members and/or purchases by Utah residents.

cc. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by class members and/or purchases by Vermont residents.

dd. W. Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by class members and/or purchases by West Virginia residents.

ee. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by class members and/or purchases by Wisconsin residents.

131. Plaintiff and the members of the damages class have been injured in their business or property by reason of Allergan's unlawful monopolization of the Restatis market. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid but for Allergan's violations. These injuries are of the type that the foregoing laws are intended to prevent, and flow from that which makes Allergan's conduct unlawful.

132. Plaintiff and the damages class seek damages and multiple damages from Allergan as permitted by law, in an amount to be proven at trial.

SECOND CLAIM FOR RELIEF

Unfair Methods of Competition, and Unfair and Deceptive Acts, in Violation of State Consumer Protection Law

133. Sergeants incorporates the above paragraphs by reference.

134. Allergan engaged in unfair methods of competition and unfair, unconscionable, deceptive and fraudulent acts or practices to wrongfully perpetuate its Restatis patent monopoly. As a direct and proximate result of Defendants' unfair, unconscionable, deceptive, and fraudulent conduct, Plaintiff and class members were denied the opportunity to purchase generic Restasis and were forced to pay higher prices for

Allergan's branded Restatis.

135. The gravity of harm from Allergan's wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and class members could not reasonably have avoided injury from Allergan's wrongful conduct.

136. There was and is a gross disparity between the price that Plaintiff and class members paid for branded Restasis and the value they received. Much more affordable, bioequivalent generic versions of Restatis would have been available sooner and in greater quantity, and prices for branded Restasis would have been far lower, but for Allergan's unfair, unconscionable, deceptive, and fraudulent conduct.

137. By engaging in such conduct, Allergan violated the following state consumer protection laws:

a. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas by class members and/or purchases by Arkansas residents.

b. Ariz. Code §§ 44-1255, *et seq.*, with respect to purchases in Arizona by class members and/or purchases by Arizona residents.

c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases in California by class members and/or purchases by California residents.

d. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases in D.C. by class members and/or purchases by D.C. residents.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by class members and/or purchases by Florida residents.

f. Idaho Code §§ 48-601, *et seq.*, with respect to purchases in Idaho by class members and/or purchases by Idaho residents.

g. 815 ILCS §§ 505/1, et seq., with respect to purchases in Illinois by class members and/or purchases by Illinois residents.

h. Kan. Stat. §§ 50-623, *et seq.*, with respect to purchases in Kansas by class members and/or purchases by Kansas residents.

i. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to purchases in Maine by class members and/or purchases by Maine residents.

j. Mass. Ann. Laws, ch. 93A, *et seq.*, with respect to purchases in Massachusetts by class members and/or purchases by Massachusetts residents.

k. Mich. Stat. §§ 445.901, *et seq.*, with respect to purchases in Michigan by class members and/or purchases by Michigan residents.

l. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by class members and/or purchases by Minnesota residents.

m. Mo. Stat. §§ 407.010, *et seq.*, with respect to purchases in Missouri by class members and/or purchases by Missouri residents.

n. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases in Nebraska by class members and/or purchases by Nebraska residents.

o. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases in Nevada by class members and/or purchases by Nevada residents.

p. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases in New Hampshire by class members and/or purchases by New Hampshire residents.

q. N.M. Stat. §§ 57-12-1, et seq., with respect to purchases in New Mexico by class members and/or purchases by New Mexico residents.

r. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases in New York by class members and/or purchases by New York residents.

s. N.C. Gen. Stat. §§ 75-1.2, *et seq.*, with respect to purchases in North Carolina by class members and/or purchases by North Carolina residents.

t. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases in Oregon by class members and/or purchases by Oregon residents.

u. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases in Pennsylvania by class members and/or purchases by Pennsylvania residents.

v. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases in Rhode Island by class members and/or purchases by Rhode Island residents.

w. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases in South Dakota by class members and/or purchases by South Dakota residents.

x. Tenn. Code §§ 47-18-101, *et seq.*, with respect to purchases in Tennessee by class members and/or purchases by Tennessee residents.

y. Utah Code §§ 13-11-1, *et seq.*, with respect to purchases in Utah by class members and/or purchases by Utah residents.

z. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases in Virginia by class members and/or purchases by Virginia residents.

aa. Vt. Stat Ann. 9, § 2453, *et seq.*, with respect to purchases in Vermont by class members and/or purchases by Vermont residents.

bb. W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases in West Virginia by class members and/or purchases by West Virginia residents.

138. On behalf of itself and the damages class, Sergeants seeks all appropriate relief provided for under the foregoing statutes.

THIRD CLAIM FOR RELIEF

Unjust Enrichment Under the Laws of All States and Territories Except Ohio and Indiana

139. Sergeants incorporates the above paragraphs by reference.

140. Allergan has reaped and retained substantially higher profits due to its unjust scheme to monopolize the market for Restatis.

141. The financial benefits to Allergan from its wrongful conduct are traceable to overpayments for Restasis by Plaintiff and class members.

142. Plaintiff and class members have conferred upon Allergan an economic benefit—its profits stemming from anticompetitive overcharges. Plaintiff and class members paid those monopoly overcharges to their substantial economic detriment.

143. Plaintiff and the class have no adequate remedy at law.

144. It would be futile for Plaintiff and the class to seek relief against the

intermediaries in the distribution chain from which they directly purchased Restasis.

145. The financial benefits that Allergan derived by charging supracompetitive prices for Restasis directly and proximately resulted from Allergan's unjust practices described herein. Those benefits rightfully belong to Plaintiff and the class.

146. It would be wrongful and inequitable, under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for Allergan to be permitted to retain any of its ill-gotten gain from its wrongful monopolization scheme.

147. Allergan should be compelled to disgorge in a common fund for the benefit of Plaintiff and the class all proceeds that it inequitably derived from its scheme, and a constructive trust should be imposed upon such sums.

FOURTH CLAIM FOR RELIEF
Injunctive and Declaratory Relief Under the Clayton Act

148. Sergeants incorporates the above paragraphs by reference.

149. In addition to violating the foregoing state laws, Allergan violated sections 1 and 2 of the Sherman Act by reason of its conduct described herein. Allergan's ongoing section 1 violations include its anticompetitive agreement with the Mohawk Tribe.

150. Plaintiff and the class will continue to suffer injury, in the form of monopoly overcharges paid for Restatis, if Allergan's unlawful conduct is not enjoined.

151. As provided under Rule 57 and 28 U.S.C. § 2201, Plaintiff and the class seek a declaratory judgment that Allergan's anticompetitive acts and practices violate Sections 1 and 2 of the Sherman Act.

152. Plaintiff and the class seek equitable and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, to correct for the anticompetitive market effects caused by Allergan's violations and to forbid Allergan from committing similar violations in the future.

XIII. PRAYER FOR RELIEF

WHEREFORE Plaintiff, on behalf of the class, prays for judgment via Court orders:

A. Providing for expedited discovery to ensure a prompt trial on the merits before a jury on all claims and defenses;

B. Determining that this action may be maintained as a class action under Fed. R. Civ. P. 23(a), (b)(1), (b)(2) and (b)(3), directing that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and appointing Sergeants as a named representative of the class;

C. Entering judgment against Allergan and in favor of Sergeants and the class;

D. Awarding treble damages (three times overcharges paid) in an amount to be determined at trial, plus interest in accordance with law;

E. Awarding Sergeants and the class their costs of suit, including reasonable attorneys' fees, as permitted by law;

F. Declaring that Allergan's anticompetitive acts and practices violate Sections 1 and 2 of the Sherman Act;

G. Granting injunctive relief to correct for the anticompetitive market effects caused by Allergan's unlawful acts and to forbid Allergan from committing such acts in the future; and

H. Entering such other and further relief as may be just and proper.

XIV. DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff, on behalf of itself and the class, demands a trial by jury on all issues so triable.

Dated: December 14, 2017

Respectfully submitted,

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